UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS

IN RE: TESTOSTERONE REPLACEMENT THERAPY PRODUCTS LIABILITY LITIGATION	MDL No. 2545
THIS DOCUMENT RELATES TO: *Tracy Garner v. Eli Lilly and Company; Lilly USA, Inc.* Case No. 1:15-cv-2045	Master Docket Case No. 1:14-cv-01748 Honorable Matthew F. Kennelly

DEFENDANTS' STATEMENT PURSUANT TO LOCAL CIVIL RULE 56.1 IN SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT ON STATE LAW GROUNDS

Pursuant to Federal Rule of Civil Procedure 56 and Local Rule 56.1, Defendants Eli Lilly and Company and Lilly USA, LLC (erroneously sued and served as Lilly USA, Inc.) (collectively, "Lilly") submit the following statement of material facts in support of the Lilly Defendant's Motion for Summary Judgment Or, In the Alternative, Partial Summary Judgment, as to Plaintiff Tracy Garner.

1. Plaintiff Tracy Garner is 50 years of age and resides in Phenix City, Alabama. (Declaration of Eric J. Buhr ("Buhr Dec.") Ex. 1 (Plaintiff Fact Sheet ("PFS")) at p. 3; Buhr Dec. Ex. 2 (Deposition of Tracy Garner ("Plaintiff's Dep.")) at pp. 23:21-24:2).

2. Plaintiff's medical history reflects a long history of cardiovascular difficulties and risk factors, including:

   a. Smoking – at least one pack of cigarettes a day since 1986 (PFS at p. 8; Plaintiff's Dep. at p. 80:9-24);

b. Stroke (Buhr Dec. Ex. 3 (Deposition of James Zumstein, M.D. ("Zumstein Dep.")) at p. 54:13-24; Plaintiff's Dep. at pp. 44:22-46:2);

c. High blood pressure (Zumstein Dep. at p. 56:4-9);

d. High cholesterol and high triglycerides and high cholesterol (*Id.* at pp. 61:19-62:1);

e. Dyslipidemia, or an abnormal amount of lipids in the blood (*Id.* at pp. 61:19-62:1); and

f. A family history of hypertension (mother) and death from heart disease (father). (PFS at p. 3; Zumstein Dep. at p. 56:14-22.)

3. Plaintiff visited Dr. James Zumstein, his primary care physician, on January 29, 2013, complaining of generalized fatigue and lack of energy. (Zumstein Dep. at p. 53:12-20).

4. Before his appointment, Plaintiff had seen a commercial that talked generally about low testosterone without referring to a particular product. (Plaintiff's Dep. at p. 17:4-22).

5. Plaintiff specifically asked Dr. Zumstein if his fatigue could be the result of low testosterone. (Zumstein Dep. at p. 55:14-21).

6. Dr. Zumstein sent Plaintiff for blood work and prescribed Lisinopril for his high blood pressure. (*Id.* at pp. 59:17-60:3).

7. The blood work showed a testosterone level of 294 ng/dl, which was well below normal range (348 – 1197). (Zumstein Dep. at p. 61:2-18).

8. Dr. Zumstein noted on the lab results that "Testosterone level is low – received Axiron." (Buhr Dec. Ex. 5 (Lab Results for Plaintiff Garner, January 29, 2013)).

9. He believed that Plaintiff was an appropriate candidate for Axiron® because of his low testosterone serum level and associated symptoms. (Zumstein Dep. at pp. 148:3-149:25).

10. In the years preceding Plaintiff's visit, Dr. Zumstein received regular visits from Lilly's sales representatives. (Zumstein Dep. at pp. 115:16-116:5).

11. But he does not, however, recall any specific conversations with Lilly's sales representatives about Axiron®:

> Okay. Do you have any specific recollection of any discussions that you've had with any sales representatives from Eli Lilly with respect to Axiron?
> A. I don't recall any specific discussions.
> Q. Do you recall if whether or not any sales representatives would provide you with any materials with respect to Axiron?
> A. I would imagine that they've left some literature in the past on Axiron.
> . . .
> Q. Okay. And you don't have any specific recollection of what -- what type of -- or what articles or what specific materials they provided?
> A. It was usually something that was probably covered in the PDR.

(Zumstein Dep. at p. 49:5-23).

12. At the time of Plaintiff's prescription, Dr. Zumstein's customary practice was to warn his patients of several potential risks of testosterone, including skin irritation, polycythemia, slight blood pressure elevation, and temporal muscles. (Zumstein Dep. at pp. 33:24-34:20, 35:1-22, 35:1-22, 65:7-16).

13. He does not recall advising Plaintiff of a cardiovascular ("CV") risk specific to myocardial infarction. (Zumstein Dep. at p. 111:7-11).

14. Plaintiff filled his prescription for Axiron® on March 7, 2013. (Zumstein Dep. at pp. 65:22-66:6).

15. He did not read the entire medication guide, although he recalled seeing the warning relating to secondary exposure on the pharmacy leaflet accompanying his prescription. (Plaintiff's Dep. at pp. 13:24-15:9).

16. He used Axiron® for four days—from Thursday, March 7 until Sunday, March 10, 2013. (Plaintiff's Dep. at p. 12:5-7).

17. He experienced chest pains on March 10 (Plaintiff's Dep. at p. 61:8-12; Zumstein Dep. at pp. 69:24-70:8) and decided to stop taking Axiron® at this time. (Plaintiff's Dep. at p. 12:1-9).

18. Three days later, on March 13, Plaintiff went to see Dr. Zumstein because his chest pains persisted. (Plaintiff's Dep. at pp. 61:8-12, 62:7-11; Zumstein Dep. at pp. 67:4-68:4).

19. Dr. Zumstein did an EKG, diagnosed a myocardial infarction (heart attack), and sent Plaintiff to St. Francis Hospital Emergency Room, where the myocardial infarction diagnosis was confirmed. (Plaintiff's Dep. at pp. 62:12-63:5; Zumstein Dep. at pp. 67:4-68:4; Buhr Dec. Ex. 4 (Deposition of Zulfiquar Bhatti ("Bhatti Dep.")) at p. 30:2-7).

20. Tests showed that Plaintiff had a 100% occlusion in the mid-circumflex artery, 70% occlusion in the left anterior descending artery, and 40% occlusion in the right coronary artery. (Bhatti Dep. at p. 37:6-13).

21. Because of his 100% occlusion, Plaintiff had a cardiac catheterization with thrombectomy and stenting of the mid circumflex artery that same day. (Bhatti Dep. at pp. 35:13-37:13).

22. He was discharged on March 15 and told to schedule a follow-up surgery to stent the left anterior descending artery. (Plaintiff's Dep. at p. 64:14-15; Bhatti Dep. at p. 45:11-16).

23. Plaintiff had that surgery (for the 70% occlusion) on July 1, 2013, without incident. (PFS at pp. 7, 11; Bhatti Dep. at pp. 53:7-55:6).

24. Since then, Plaintiff has had no recurrence of the myocardial infarction or complications, no work restrictions, has worked without any problems, and rides his motorcycle. (Plaintiff's Dep. at pp. 34:14-36:20, 88:5-17; Bhatti Dep. at pp. 70:2-10, 71:14-21).

25. His treating cardiologist believes he has a good prognosis if he continues to take care of himself. (Bhatti Dep. at pp. 71:22-72:2).

26. At the time he was deposed in early 2017, Dr. Zumstein was still prescribing Axiron® for his patients. (Zumstein Dep. at p. 43:7-10).

27. While he testified that additional information about CV risks related to its product might have affected his prescribing practices with respect to Axiron® or the warnings he might have given to his patients generally, (Zumstein Dep. at pp. 131:12-132:4), Dr. Zumstein made it clear that Plaintiff was an appropriate patient to receive Axiron®, he would still prescribe it for him today, and still give the very same warnings he gave Plaintiff at the time:

> Q. Okay. And would it be fair to say that in your opinion Mr. Garner was an appropriate patient to receive Axiron?
> A. Yes, uh-huh.
> Q. Okay. Again, based on Mr. Garner's presentation to you, if he presented with low testosterone complaints, symptoms of fatigue, do you feel he would still be an appropriate patient if he presented to you today?
> A. Yes, uh-huh.
> Q. Okay. And it's fair to say that your discussions with him today would be consistent with what you discussed with him when you prescribed in January 2013 with respect to the risks and benefits of Axiron; true?
> A. Yes.

(Zumstein Dep. at p. 171:9-24).

> Q. Okay. So, again, fair to say that when -- because you're currently discussing with your patients -- you don't affirmatively bring up cardiovascular risk when prescribing testosterone replacement therapy. If prescribing testosterone replacement therapy to Mr. Garner today, that's not something you would affirmatively bring up with him; true?
> A. Well, I -- you know, the package insert just says patient should be informed of possible risk when deciding when to continue using or to use. So that may be something I might -- I might bring up.
> Q. Okay. But up -- up to this point in time in your practice, you haven't advised -- you have not advised your patients of that; true?
> A. True.
> Q. Okay. So all the way up until today, that's fair to say that the -- the discussion you had with Mr. Garner when you prescribed Axiron for him, that would be consistent with the discussion you would have with him up to today if you were prescribing for him?
> A. Yes.

(*Id.* at p. 186:4-25).

28. Defendant Eli Lilly and Company is a corporation organized and existing under the laws of Indiana with its principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285. Plaintiff's Fourth Amended Master Long-Form Complaint and Jury Demand (Doc. 1345) filed in *In re Testosterone Replacement Therapy Prods. Liab. Litig.*, No. 14-cv-1748 (June 14, 2016), at para. 29.

29. Defendant Lilly USA, LLC is a limited liability company operating as a wholly-owned subsidiary of Defendant Eli Lilly and Company, with its principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285. Plaintiff's Fourth Amended Master Long-Form Complaint and Jury Demand (Doc. 1345) filed in *In re Testosterone Replacement Therapy Prods. Liab. Litig.*, No. 14-cv-1748 (June 14, 2016) at para 30.

Dated: November 21, 2017

By: */s/ David E. Stanley*

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CERTIFICATE OF SERVICE

I, David E. Stanley, certify that on November 21, 2017, I served a true and correct copy of the foregoing **DEFENDANTS' STATEMENT PURSUANT TO LOCAL CIVIL RULE 56.1 IN SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT ON STATE LAW GROUNDS** on all counsel of record by electronic notice through the CM/ECF system of the United States District Court for the Northern District of Illinois.

/s/ David E. Stanley
David E. Stanley